CYSTATIN C CONTROL

For discrete analyzers
Product code: **1478-0591**
Package: **3 x 2ml Level 1**
3 x 2ml Level 2
Storage: **2-8°C**
For *in vitro* use only

INTENDED USE

Material for the quality control of the determination of Cystatin C with MEDICON reagents on MEDILYZER®, Diatron Pictus series, BECKMAN COULTER AU400/600/600-IVD/640/2700/5400, ADVIA 1200/1800/2400, DIMENSION® RxL /RxL HM /RxL Max/RxL Max HM/ Xpand/ Xpand HM/Xpand Plus/Xpand Plus HM/ EXL/EXL LOCI Module and every other automated biochemical analyzer that reference ranges have been determined and are mentioned in the appropriate leaflet. For in vitro use only.

COMPOSITION

Human Cystatin C in buffer. Stabilizers and preservatives.

WARNINGS – PRECAUTIONS

- For in vitro use only.
- Every donor used for the preparation of the material was tested and found negative for HbsAg, anti-HCV and anti-HIV 1 and 2 with FDA approved methods. As there is no known test method that can offer complete assurance that products derived from human blood will not transmit infectious agents this product should be handled as a potentially infectious material.
- Contains sodium azide (NaN3) <0.1% as preservative. Avoid contact with skin, eyes and mucous membranes.

PREPARATION

Product ready to use. Shake gently before use. Avoid foaming. Replace cap immediately after use and store at 2-8°C. Unsuitable storage, handling, or errors during the analytical procedure may give erroneous results.

MATERIALS NEEDED BUT NOT PROVIDED WITH THE KIT

No reagents or materials needed, other than the automated biochemical analyzer and the Cystatin C reagents.

STORAGE – STABILITY

Unopened, the material is stable up to the expiry date stated on the label at 2-8°C. After opening, the material is stable for 1 month, when stored tightly capped, at 2-8°C.

TEST PROCESS

Refer to the user's manual of the analyzer for calibration and quality control process.
Each laboratory should establish its own control frequency, however good laboratory practice suggests that controls be tested each date patient samples are tested and each time calibration is performed.
The results obtained by any individual laboratory may vary from the given mean value but should fall within the corresponding acceptable ranges given in the enclosed table.
If any trends or sudden shifts in values are detected, review all operating parameters. Each laboratory should establish guidelines for corrective actions to be taken if controls do not recover within the specified limits. Make sure the LOT on the vial is the same as on the value sheet accompanying the material.

WASTE DISPOSAL

Contains sodium azide (NaN3) < 0.1%. Sodium azide forms explosive compounds with lead or copper. Flush waste pipes with plenty of water after disposal of undiluted material to avoid sodium azide build up in the drain. Dispose of all material according to local guidelines for potentially infectious materials. Material safety data sheet is available by MEDICON on request.

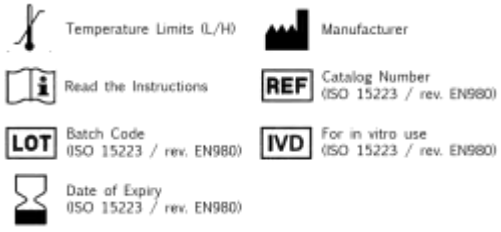
ASSIGNED VALUES – Lot specific

Refer to the table of assigned values. The range represents the maximum acceptable deviation for one measurement only.

ΒΙΒΛΙΟΓΡΑΦΙΑ

1. Blirup-Jensen S, Johnson AM, Larsen M. Protein standardization IV: value transfer procedure for the assignment of serum protein values from a reference preparation to a target material. Clin Chem. Lab Med 2001; 39:1110-1122.
2. Baudner S, Bienvenu J, Blirup-Jensen S, Carlström A, Johnson AM, Milford Ward A, et al. The certification of a matrix reference material for immunochemical measurement of 14 human serum proteins. CRM 470. EUR 15243 EN, 1993.

SYMBOLS



CE IVD

MEDICON HELLAS S.A. - Melitona 5-7, 153 44 Gerakas, Greece. Tel: +302106606000 - Fax: +302106612666 – www.mediconsa.com

Version 01 Last updated: 28/08/2015